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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,316	12/20/2001	Mieke Sibeijn	253.182	4410

7590 02/03/2004

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New York, NY 10016

EXAMINER

PRATS, FRANCISCO CHANDLER

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 02/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/029,316	<b>Applicant(s)</b> SIBEIJN ET AL.	
	<b>Examiner</b> Francisco C Prats	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

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**DETAILED ACTION**

The amendment filed October 31, 2003, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claims 1 and 3-14 are pending and are examined on the merits.

***Claim Rejections - 35 USC § 103***

Claims 1, 2-9 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jaeger (U.S. Pat. 3,268,606) in view of Sarnecki (U.S. Pat. 3,356,753).

Jaeger discloses a process of preparing  $\beta$ -carotene from *Blakeslea trispora* wherein the biomass is treated with the claimed solvents, the biomass is extracted with a water immiscible solvent, and the  $\beta$ -carotene is then crystallized in an organic solvent. See col. 1, line 45 through col. 2, line 43. Jaeger differs from the claims in not using a water wash to obtain the crystals by floating.

However, Sarnecki clearly discloses that solvent-extracted  $\beta$ -carotene is readily crystallized in water in a highly pure form. See, e.g. col. 3, lines 61-64; see also Example 14, at col. 6, lines 29-36. Thus, the artisan of ordinary skill at the time of applicant's invention clearly would have recognized that

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Sarnecki's water-based method of crystallization would have functioned at least equivalently to Jaeger's organic solvent-based crystallization method, and would therefore have been motivated to have used Sarnecki's method of crystallization in Jaeger's  $\beta$ -carotene purification method. Clearly from the disclosure of the two references the artisan of ordinary skill would have had a reasonable expectation that Sarnecki's crystallization would have functioned at least equivalently to Jaeger's crystallization.

Note specifically that the use of an oil, recited in claims 7 and 9, is considered obvious in view of Sarnecki's disclosure of the use of polyethoxy castor oil as a  $\beta$ -carotene extractant. Note further that the step of bubbling gas through the washing medium, recited in claim 8, is considered obvious in light of Sarnecki's disclosure that the water wash for crystallization is stirred for a significant length of time (e.g. 60 hours in Example 14 at col. 6), the claimed use of aeration being an equivalent method of agitating the crystallization milieu. Thus, a holding of obviousness is clearly required.

Claims 1, 2-9 and 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jaeger (U.S. Pat. 3,268,606) in view of Sarnecki (U.S. Pat. 3,356,753) as applied to claims 1, 2-9

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and 11-13, and further in view of Rose et al (U.S. Pat. 5,378,369) and Bohinski et al (U.S. Pat. 3,492,202).

As discussed above, Jaeger when taken in view of Sarnecki clearly renders obvious claims 1, 2-9 and 11-13. Neither Jaeger nor Sarnecki discloses the use of vegetable oil at the various times of the extraction process as recited in claims 7 and 10. However, Bohinski clearly provides motivation for adding vegetable oil to the microbial cells before cell disruption, by noting that yields are improved when this is done. See sol. 1, lines 47-53. Moreover, Rose clearly provides motivation for adding oil to the cells after disruption, and even in the crystallization step, by disclosing that vegetable oil is an efficient extractant for  $\beta$ -carotene. Thus, a holding of obviousness over the limitations in claim 14 is clearly required.

#### ***Response to Arguments***

All of applicant's argument regarding the pending grounds of rejection has been fully considered but is not persuasive of error. Applicant is correct in asserting that the cited references disclose processes wherein the carotenoids are solubilized and then crystallized. However, it is respectfully submitted that, despite the present amendment to the claims, the

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claims as amended are still sufficiently broad to encompass the processes suggested by Jaeger, Sarnecki and the other cited references.

Specifically, Jaeger discloses processes whereby cells of the fermented biomass are disrupted by mixing with alcohol, and then filtered. See column 3, lines 5-11. Jaeger therefore discloses the steps of "disrupting the microbial cell walls" and "separating cellular debris from the resulting carotenoid crystal containing residue" recited in claim 1. Note that, in the same way as in applicant's examples, carotene crystals would be present in view of the fact that the carotene is insoluble in the methanol used in the disruption step. Jaeger later discloses crystallizing the carotene by evaporating the extracting solvent, and then adding ethanol, the exact lipid removing solvent recited in claims 4 and 13. Thus, the only step not disclosed by Jaeger is the floating of the crystals in water. However, as discussed above, Sarnecki discloses the suitability of water as a carotene crystallizing agent, thereby rendering obvious the claimed process.

It is noted, as argued by applicant, that a solvent extraction step (i.e. solubilization step), using methylene chloride for example, intervenes between Jaeger's debris removal step and crystal washing step. However, applicant's process is

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recited in open "comprising" language. Such language does not exclude additional non-claim-recited process steps, such as the extraction steps disclosed by Jaeger. Thus, contrary to applicant's argument, the process as claimed is suggested by Jaeger.

Looking at applicant's claims 5-7, it is particularly evident that applicant's claims encompass the solvent extraction steps of Jaeger. Claim 5 clearly states that a water immiscible solvent is added to the microbial cells before, during or after cell wall disruption, with claim 6 limiting the solvent addition to after cell wall disruption. This is exactly what Jaeger does. See, e.g., column 2, lines 22-36, disclosing the use of water immiscible solvents as extracting agents for the carotene after the cell wall disruption, followed by crystallization of the carotene. Thus, despite applicant's argument that the claims as amended distinguish from the cited prior art, it is respectfully submitted that the claims are sufficiently broad to encompass the processes suggested by the cited prior art. The rejections must therefore be maintained.

No claims are allowed.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 571-272-0921. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

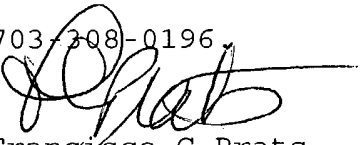
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can



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be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-208-0196.



Francisco C Prats  
Primary Examiner  
Art Unit 1651

FCP